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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/596,746

Applicant(s)

DATTWYLER ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2January2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 14-38 and 44-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 39-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 2 January 2002, paper #8, is acknowledged.

Applicants elect, with traverse, Invention I, claims 1-13, and 39-43, drawn to polypeptides, classified in class 424, subclass 185.1.

The traversal is on the grounds that the independent claims of Inventions II and III require the same elements as found in claim 1, and it is the composition that provides inventiveness to the method of immunizing and the method of detecting. In addition, a search of Inventions II and III primarily requires a search of the composition claimed in claim 1, thus there would be no serious burden on the Examiner. This is not found persuasive because the inventions are distinct as shown by their different classification, and because while the searches may overlap, the searches are not coextensive. The requirement is still deemed proper and is therefore made FINAL.

Claims 14-38 and 44-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Applicants elect SEQ ID NO:30 in response to the requirement for an election of species.

2. Claims 1-13 and 39-43 are under consideration.

### Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

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### Specification

4. The disclosure is objected to because of the following informalities:
- a) throughout the specification, *B. burgdorferi* appears with burgdorferi beginning with a capital B and a lower case b, the correct form is lower case b,
- Appropriate correction is required.

### Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 1-13 and 39-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein compositions comprising *B. burgdorferi sensu stricto* OspC proteins LipCB31, LipC12, UnlipC2, UnlipC2C7, UnlipC2C10, Unlip C2C12, UnlipC5C10, and UnlipC5C12, does not reasonably provide enablement for compositions comprising OspC from other *Borrelia*, or immunogenic fragments thereof. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - compositions comprising OspC polypeptides or immunogenic fragments thereof from  $\geq 2$  *B. burgdorferi* OspC families or *B. afzelii*.

The state of the prior art - the prior art and the instant specification teach that there are three pathogenic genospecies of *B. burgdorferi*, i.e., *B. burgdorferi sensu stricto*, *B. afzelii*, and *B. garinii*, all of which are members of a species complex *B. burgdorferi sensu lato*, which consists of  $\geq 10$  different genospecies. Therefore, the broad term *B. burgdorferi* denotes many different genospecies.

The amount of direction or guidance present - the specification teaches production of whole OspC from only *B. burgdorferi sensu stricto*, and teaches immunizing mice only with *B. burgdorferi sensu stricto* OspC proteins LipCB31, LipC12, UnlipC2, UnlipC2C7, UnlipC2C10,

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Unlip C2C12, UnlipC5C10, and UnlipC5C12. The specification does not teach or provide guidance for fragments of these listed proteins.

The quantity of experimentation necessary to fulfill the scope of these claims constitute merely an invitation to experiment without a reasonable expectation of success even though the relative skill of those in the art is high for protein isolation and production.

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is drawn to  $\geq 1$  OspC polypeptide from each family. It is unclear if the claim means that each family has more than one OspC.

9. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is drawn to chimeric OspC protein selected from a group consisting of SEQ ID Nos. However, it is unclear what chimeric protein is SEQ ID NO:58 or SEQ ID NO:68 as there appears to be no mention of either protein by these SEQ ID Nos in the specification.


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**Conclusion**

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

March 25, 2002